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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/063,711 | 05/08/2002 | Dan L. Eaton | P3230R1C001-168 | 8521 |

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| EXAMINER | |
|---|---|
| KAUFMAN, CLAIRE M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/063,711 | EATON ET AL. | |
| | Examiner | Art Unit | |
| | Claire M. Kaufman | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 May 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/17/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC §§ 101/112*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn narrowly to a nucleic acid of SEQ ID NO:77 or broadly to a nucleic acid at least 80% identical to a nucleic acid encoding an extracellular domain of SEQ ID NO:78. The specification asserts a number of utilities for the encoding nucleic acid, however, these utilities are not specific and substantial or well established. Because there is neither a known physiological or clinical significance of the polypeptide, and the prior art does not support a very close structural relationship to a well described (structurally and functionally) family of known proteins, the encoding nucleic acid cannot derive a utility from the encoded polypeptide.

An asserted utility is in drug screening and rational drug design. The method involves screening for "agents which can affect a PRO polypeptide-associated disease or disorder" (p. 135, ¶[0507]). No disease or disorder is known to be associated with the claimed polypeptide or encoding nucleic acid. The use of a nucleic acid in an array for screening is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. This is a utility which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNAs. Even if the expression of the claimed nucleic acid is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this

consideration, the individually claimed nucleic acid has no "well-established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what use any expression information regarding this nucleic acid could be put.

Another possible utility comes for the finding that the encoding polynucleotide is "more highly expressed" in normal stomach and lung as compared to stomach and lung tumor tissue (Example 18, p. 142). There is no guidance on how to use this information. No levels (relative or absolute) are disclosed. This information is too sparse to allow the encoding polynucleotide to be used as a diagnostic marker for stomach or lung tumor. Because it is not known if the nucleic acid is involved in causing (or suppressing) the tumor, the skilled artisan could not use it therapeutically as target for treatment of a tumor. It is noted that even if the nucleic acid had utility as a tumor marker, the encoded polypeptide would have no such utility since there is no reason to suspect that there is alteration of polypeptide sequence or amount in stomach or lung tumor *versus* normal tissue.

For these reasons, there is no substantial and specific utility for the nucleic acid of SEQ ID NO:77.

Claims 22-34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

It would require significant further experimentation to be able to use the claimed nucleic acid because no definite function has been determined for the encoded protein and there is no definite function supported by the prior art. The specification does not provide sufficient guidance or working examples to be able to use the nucleic acid diagnostically or therapeutically, for example in association with stomach or lung tumors, to be able to use the claimed invention without undue experimentation.

Claims 1-6, 9, 10 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acids having at least 80%, 85%, 90%, 95% or 99% sequence identity with a particular disclosed sequence. The claims do not require that the nucleic acid or encoded polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Which nucleic acids of the genus comprising the required sequence are part of the invention has not been set forth.

Other claims are drawn to a nucleic acid encoding the extracellular domain of the polypeptide of SEQ ID NO:78 (with our without its signal sequence), even though no extracellular domain has been described. While a signal peptide was identified as amino acids 1-21 of SEQ ID NO:78, the specification does not provide information about if the protein is transported to/through the cell's membrane. Similarly, while there are glycosaminoglycan attachment sites, it is not clear that those sites are used and their identification does not support the description of an extracellular domain. Even if the sites are on an extracellular portion of the protein, which amino acids make up the extracellular domain have not been described. Therefore, a nucleic acid encoding an extracellular domain has not been described.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid comprising the sequence set forth in SEQ ID NO: 77 (or the full-length coding sequence of the cDNA deposited under ATCC 203240) or encoding the polypeptide of SEQ ID NO:78 with our without its signal sequence, but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9, 10, 14, 16 and dependent claims 7, 8, 11-13, 15 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because of the recitation of "extracellular domain". There has been no extracellular domain identified. While a signal peptide was identified as amino acids 1-21 of SEQ ID NO:78, it is unclear where the signal sequence causes the protein to be transported. Similarly, even though there are glycosaminoglycan attachment sites, it is not clear

that those sites are used. Accordingly, the limitation that the claimed nucleic acid encodes an "extracellular domain" (for example see claim 1, parts (c) and (d)) is indefinite.

Claims 14-16 are also indefinite because the metes and bounds of the claims are not clear. There are no conditions of stringency discussed in claim 14. It is not clear if non-specific hybridization is included in which structural relatedness is of little consequence. Further, while the skilled artisan understands the general concept of hybridization under "stringent conditions", what specific conditions are intended by the use of the term "stringent" in claim 15 is unknown. The specification discusses stringent conditions through examples without providing a limiting definition (see ¶[0227]). What conditions of stringency are used in any particular situation are determined by the specificity of hybridization desired by the practitioner. In this case, the desired specificity is unknown. If there is a structural relatedness (limitation) that is being defined by the conditions, then those conditions or range of conditions must be clear in the claim.

### *35 U.S.C. § 102*

The following rejection under 35 U.S.C. § 102 is made under the assumption that the effective filing date for the instantly claimed invention is 05/03/2002, which is the actual filing date of the instant application. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. §120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the new claimed invention. Because the instant application does *not* meet the requirements of 35 U.S.C. § 112, first paragraph, for the reasons given above and it is a continuing application of Serial Number 10/006,867, the prior application also does not meet those requirements for the claimed invention and, therefore, is unavailable under 35 U.S.C. § 120.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/16318 or WO 00/12708.

WO 01/16318 teaches the nucleic acid of SEQ ID NO:77 (see Fig. 77), as well as a vector and host cell comprising the nucleic acid (see, for example, Example 7, pages 84-86). SEQ ID NO:77 is identical to SEQ ID NO:77 of the instant application.

WO 00/12708 teaches the nucleic acid of SEQ ID NO:127 (see Fig. 71), as well as a vector and host cell comprising the nucleic acid (see, for example, pages 292-296). SEQ ID NO:127 is identical to SEQ ID NO:77 of the instant application.

***Conclusion***

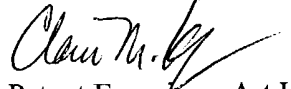
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

June 17, 2004